

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Smith et al.

Examiner: Unassigned

Serial No.: 09/691,782

Group Art Unit. 3738

Filed: October 19, 2000

Docket: 760-3 RES

For: COVERED STENT

Dated: February 16, 2001

I hereby certify that this correspondence is being deposited with United States Postal Service as first class mail, postpaid in an envelope, addressed to Assistant Commissioner For Patents, Washington, D C

20231 on February 16, 2001

Signed Barbara Kemmlein

Assistant Commissioner For Patents  
Washington, D.C. 20231

**RESPONSE TO NOTICE TO FILE MISSING PARTS  
OF REISSUE APPLICATION - FILING DATE GRANTED**

Sir:

In response to the Notice To File Missing Parts of Reissue Application mailed November 30, 2000, enclosed herewith are the following:

1. Copy of Notice to File Missing Parts of Reissue Application - Filing Date Granted.
2. Check in the amount of \$130.00 representing the surcharge fee for filing a late Declaration.
3. Check in the amount of \$808.00 representing the Filing Fee of \$710.00 and Extra Claims Fee of \$98.00.
4. Check in the amount of \$110.00 representing One Month Extension of Time fee.
5. Reissue Declaration executed by Inventors Scott R. Smith, David Sogard and Susan Shoemaker.

6. Consent of Assigning as required by 37 C.F.R. §1.172.
7. Statement under 37 C.F.R. § 3.73(b) establishing right of assignee to take action on the case.

Please charge any deficiencies or credit any overpayment in these fees to deposit account no. 08-2461. A duplicate of this transmittal is enclosed.

In view of the documents submitted herewith, Applicant respectively urges that the application is in condition for examination. Please direct any questions regarding this submission to Applicants' undersigned attorney.

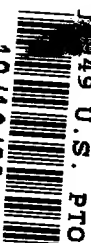
Respectfully submitted,



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10/19/00



U.S. PTO

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U.S. PTO

Practitioner's Docket No. 760-3 RES

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Date: October 19, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

REISSUE APPLICATION TRANSMITTAL

Transmitted herewith is the application for reissue of U.S.

☒ Utility Patent    ☐ Plant Patent    ☐ Design Patent  
No. 5,824,046 issued on October 20, 1998

Inventor(s): Smith, Scott, R.; Sogard, David; Shoemaker, Susan  
Title: COVERED STENT

Enclosed are the following:

1. Specification, claim(s) and drawing(s) (37 C.F.R. § 1.173)

- (a) ☒ 8 page(s) of specification
- ☒ 4 page(s) of claims
- ☒ 1 page(s) of abstract

NOTE: This must include the entire specification and claims of the patent, with the matter to be omitted by reissue enclosed in square brackets. Any additions made by the reissue must be underlined, so that the old and new specifications and claims may be readily compared. Claims should not be renumbered. The numbering of claims added by reissue should follow the number of the highest numbered patent claim. No new matter shall be introduced into the specification. (37 C.F.R. § 1.173).

CERTIFICATION UNDER 37 C.F.R. § 1.10\*  
(Express Mail label number is mandatory.)  
(Express Mail certification is optional.)

I hereby certify that this Reissue Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date October 19, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EF110941902US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Barbara Kemmlein

(type or print name of person mailing paper)

Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(b) ☒ 7 sheet(s) of drawing (drawings amended)

☐ Formal

☒ Informal

NOTE: "Amendments which can be made in a reissue drawing, that is, changes from the drawing of the patent, are restricted." 37 C.F.R. § 1.174(b).

☒ No changes in the drawings, upon which the original patent was issued, are to be made. Therefore, in accordance with 37 C.F.R. § 1.174(a), please find attached, in the size required for original drawings:

☐ a copy of the printed drawings of the patent.

☐ a photoprint of the original drawings.

☒ A letter requesting transfer of the drawings from the original patent file to this reissue application is attached.

2. Declaration and power of attorney will follow.

☐ \_\_\_\_\_ pages of declaration and power of attorney

3. Preliminary amendment

(check, if applicable)

☐ Attached

4. Offer to surrender the original letters patent in accordance with 37 C.F.R. § 1.178 is attached.

☒ Offer to surrender is by the inventor

☒ along with assent of assignee, and will follow with Declaration.

☐ Offer to surrender is by the assignee of the entire interest (and the reissue application does not seek to enlarge the claims of the original patent).

5. Letters patent

☐ Original letters patent are attached.

☐ Declaration that original letters patent lost or inaccessible is attached.

☒ A copy of the original printed patent is attached.

NOTE: "The application may be accepted for examination in the absence of the original patent or the declaration but one or the other must be supplied before the case is allowed." 37 C.F.R. § 1.178.

NOTE: "Where the original patent grant is not submitted with the reissue application as filed, patentee should include a copy of the printed original patent. Presence of a copy of the original patent is useful for the calculation of the reissue filing fee and for the verification of other identifying data." M.P.E.P., § 1416, 7th ed.

NOTE: "If a reissue be refused, the original patent will be returned to applicant upon his request." 37 C.F.R. § 1.178.

(Reissue Application Transmittal [17-1]—page 2 of 6)

6. Petition to proceed without assignee's assent

☐ Attached hereto is a "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE'S ASSENT".

A. ☐ The fee payment is authorized in the attached:

☐ "REISSUE APPLICATION TRANSMITTAL" Form

☐ "COMPLETION OF FILING REQUIREMENTS — REISSUE APPLICATION" Form.

B. ☐ Payment is authorized below.

7. Information Disclosure Statement

☐ Attached

☐ Copies of the IDS citation(s) is/are attached.

8. Priority—35 U.S.C. § 119

☐ Priority of application Application No. 0 / \_\_\_\_\_, filed on \_\_\_\_\_, in \_\_\_\_\_ is claimed under 35 U.S.C. § 119.  
Country

☐ The certified copy has been filed in prior application Application No. 0 / \_\_\_\_\_ filed on \_\_\_\_\_.

9. Basic Filing Fee Calculation (37 C.F.R. § 1.16(h), (i) and (j))

CLAIMS AS FILED			
Number Filed	Number Extra	Rate	Basic Fee (37 C.F.R. 1.16(h)) \$ 710.00
Total Claims (37 C.F.R. § 1.16(j))	21 — 20 (and also in excess of total claims in patent)	X \$18.00	18.00
Independent Claims 37 C.F.R. § 1.16(i)	4 — (number of inde- pendent claims in patent)	X \$78.00	78.00
Filing fee Calculation			\$ 968.00

NOTE: Multiple dependent claims are treated as ordinary claims for fee purposes. 37 C.F.R. § 1.16(j).

(Reissue Application Transmittal [17-1]—page 3 of 6)

**10. Small Entity Status (if applicable)**

**NOTE:** A new statement is required for the reissue, even if one has been filed in the original patent. 37 C.F.R. § 1.27(a).

**WARNING:** "Small entity status must not be established when the person or persons signing the . . . statement can **unequivocally** make the required self-certification." M.P.E.P. § 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

- ☐ A statement that this filing is by a small entity is  
☐ attached.

Filing Fee Calculation (50% of above) \$ \_\_\_\_\_

**NOTE:** If a statement is filed within 2 months of the date of timely payment of a fee, then the excess fee paid will be refunded on request. 37 C.F.R. § 1.28(a). Effective April 1, 1984.

**11. Additional Fee Payments**

- ☐ Payment is being made for "PETITION TO PROCEED WITH REISSUE APPLICATION WITHOUT ASSIGNEE"  
(37 C.F.R. § 1.17(h)) . . . . . \$130.00

**12. Total Fees Due**

Filing Fee	\$ _____
Petition fee	\$ _____
<b>Total Fees Due</b>	<b>\$ _____</b>

**13. Method Of Payment of Fees**

(X) FEE WILL FOLLOW

- ☐ Enclosed is a check in the amount of \$ \_\_\_\_\_.
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.
- A duplicate of this request is attached.

**NOTE:** Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

#### 14. Authorization To Charge Additional Fees

**WARNING:** If no fees are to be paid on filing, the following items should not be completed.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. \_\_\_\_\_ :

- ☐ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)  
☐ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

**NOTE:** Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)  
☐ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a)).  
☐ 37 C.F.R. § 1.17 (application processing fees)

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

**NOTE:** Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

**NOTE:** See 37 C.F.R. § 1.28.

#### 15. ☐ Additional Enclosures

Reg. No.: 46,150

Tel. No.: (973 ) 331-1700

Customer No.:



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**SIGNATURE OF PRACTITIONER**

Mark E. Baron, Esq.

*(type or print name of practitioner)*

HOFFMANN & BARON, LLP

P.O. Address

6900 Jericho Turnpike

Syosset, NY 11791



1  
COVERED STENT

FIELD OF THE INVENTION

The present invention relates generally to an implantable intraluminal device. More particularly, the present invention relates to a composite intraluminal device including a stent and stent cover.

BACKGROUND OF THE INVENTION

It is well known to employ various endoprostheses for the treatment of diseases of various body vessels. One type of endoprosthesis is commonly referred to as a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful in the treatment of stenosis, strictures or aneurysms in body vessels such as blood vessels. These devices are implanted within the vessel to reinforce collapsing, partially occluded, weakened or abnormally dilated sections of the vessel. Stents are typically employed after angioplasty of a blood vessel to prevent restenosis of the diseased vessel. While stents are most notably used in blood vessels, stents may also be implanted in other body vessels such as the urogenital tract and bile duct.

Stents generally include an open flexible configuration. This configuration allows the stent to be inserted through curved vessels. Furthermore, the stent configuration allows the stent to be configured in a radially compressed state for intraluminal catheter implantation. Once properly positioned adjacent the damaged vessel, the stent is radially expanded so as to support and reinforce the vessel. Radial expansion of the stent may be accomplished by inflation of a balloon attached to the catheter or the stent may be of the self-expanding variety which will radially expand once deployed. Examples of various stent constructions are shown in U.S. Pat. Nos. 4,503,569 to Dotter; 4,733,665 to Palmaz; 4,856,561 to Hillstead; 4,580,568 to Gianturco; 4,732,152 to Wallsten and 4,886,062 to Wiktor, each of which are incorporated by reference herein. Additionally, published PCT WO96/26689 entitled "Improved Longitudinally Flexible Expandable Stent", and its priority U.S. applications 08/396,569 filed Mar. 1, 1995 and 08/511,076 filed Aug. 3, 1995 are also incorporated by reference herein.

While the stents of such construction perform adequately for the purpose of holding open otherwise blocked, weakened or occluded vessels, due to the open nature of the stent there is a tendency for the stent to permit passage of material through the body of the stent. Such material may include excessive cell or tissue growth (intimal hyperplasia), thrombus formations and plaque in vascular situations and tumors in the bile or urogenital tract. These materials may have a tendency to block or otherwise re-occlude the open vessel.

One technique to reduce the susceptibility for materials to pass through the wall of the deployed stent includes providing a composite intraluminal device including a stent and an outer covering which would surround the open stent construction. While such covers would prevent material from passing through the stent wall, the covering itself must be sufficiently flexible and expandable so as to permit deployment of the stent from its compressed condition to its radially expanded condition.

Examples of composite intraluminal devices are described in the following U.S. patents.

U.S. Pat. No. 5,123,916 to Lee describes an expandable intraluminal vascular graft which includes concentric cylindrical tubes having a plurality of scaffold members mounted

there between. The scaffold members are expandable, ring-like and provide circumferential rigidity to the graft.

U.S. Pat. No. 5,383,926 to Lock, et al. describes a radially expandable endoprosthesis which comprises an elongated sleeve member in which the radially outward expansion of the sleeve is limited by connecting strips. These strips are selectively removable to allow further outward expansion. The sleeve can be C-shaped in cross-section to allow for further expanded growth. The sleeve member generally has an open wall structure such as those typical of wire mesh tubing or slotted tubing. An expandable sheet material may be disposed across the open region of the C-shaped sleeve member and may be formed of Goritex®.

U.S. Pat. No. 5,389,106 to Tower discloses an impermeable expandable intravascular stent. An impermeable deformable membrane interconnects portions of a distensible frame to form an impermeable exterior wall to the frame. The membrane is formed of a synthetic non-latex, non-vinyl polymer and the frame is made from a fine wire of annealed platinum. The distensible frame may be an expandable stent and the membrane is a hypoallergenic biologically inert material that is free of latex rubber proteins. The membrane should be impermeable and have the properties of elasticity, distensibility and barrier protection. No specific classes of materials are mentioned except the product name Tactylon®. The impermeable membrane is attached to the stent by dipping the stent into the polymer solution of the membrane and subsequently drying the device to remove the solvent. The stent is imbedded within the membrane surface.

Another type of covered stent which permits radial expansion is shown in WO 96/00103 having an international publication date of Jan. 4, 1996. As shown and described therein, a metallic expandable stent includes an outer covering of ePTFE. The ePTFE cover exhibits suitable expansion capabilities so as to enable the cover to expand upon expansion of the underlying stent. However, in order to impart the expandable characteristics to the ePTFE cover, during formation the ePTFE material forming the cover must undergo the successive processing steps of expanding the material, sintering the material, radially dilating the material and resintering the dilated material. The ePTFE cover so formed is sufficiently expandable so as to enable the cover to exhibit the required expansion characteristics. However the device described above requires precise manufacturing techniques and is extremely processing sensitive. Careful processing of the material forming the cover is required in order for the cover to exhibit sufficient expansion capabilities. It is therefore desirable to provide a covered stent where the cover is radially expandable with the stent and where the cover may be easily manufactured and applied to the stent.

#### SUMMARY OF THE INVENTION

It is an object of the present invention to provide an intraluminal prosthetic device such as a stent which will hold open an occluded, weakened or damaged vessel.

It is a further object of the present invention to provide a covered stent for intraluminal use which is designed to hold open a damaged lumen and to prevent material passage through the body of the stent.

It is a still further object of the present invention to provide an expandable covered stent which may be deployed intraluminally wherein the cover of the stent expands with the expansion of the stent.

In the efficient attainment of these and other objects, the present invention provides a composite intraluminal device

including an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis. A stent cover is formed of unsintered ePTFE which is expandable and which is positioned about the stent for expansion with the radial expansion of the stent.

In one preferred embodiment, the stent cover includes a longitudinal segment of unsintered ePTFE generally aligned longitudinally along the longitudinal stent axis. The longitudinal segment is expandable in a transverse direction upon radial expansion of the stent.

In a further embodiment of the invention, the stent cover includes an elongate segment of unsintered ePTFE having an original longitudinal expanse. The segment is expanded in a transverse direction so as to reduce the original longitudinal expanse. The cover is positioned generally transverse to the longitudinal stent axis. The expanded segment is expandable longitudinally upon radial expansion of the stent to return the expanded segment to the original longitudinal expanse to control the radial expansion of the stent. Further in this embodiment, the cover may be positioned with respect to the stent in a manner where the longitudinal stent axis lays orthogonally (i.e. at an acute off axis angle) with respect to the cover.

In a method aspect, the present invention provides a method of forming an intraluminal device. The method includes the step of providing an elongate radially expandable tubular stent. An elongate stent cover is formed of unsintered ePTFE. The stent cover is expandable in a transverse direction. The stent cover is applied about the stent so as to prevent transverse expansion of the cover upon radial expansion of the stent.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective showing of the composite intraluminal device of the present invention.

FIG. 2 is a perspective showing of a stent of the type which may be used in the composite device shown in FIG. 1.

FIG. 3 is a perspective showing of a stent cover employed in the composite device shown in FIG. 1.

FIG. 3A is a photomicrograph of uniaxially oriented ePTFE material of the type forming the cover of FIG. 3.

FIG. 4 is a cross-sectional view of one embodiment of the covered stent of the present invention shown in the compressed condition.

FIG. 5 is a cross-sectional view of the covered stent of FIG. 3 shown in the radially expanded condition.

FIG. 6 is a perspective showing of a cover employed in a further embodiment of the present invention.

FIG. 6A is a photomicrograph of ePTFE material of the type forming the cover of FIG. 6, which has been transversely expanded.

FIG. 7 shows the cover of FIG. 5 in a transversely expanded condition.

FIG. 8 is a schematic representation of the cover of FIG. 6 applied about the stent.

FIG. 9 is a cross-sectional view of the further embodiment of the present invention shown in a compressed state.

FIG. 10 is a cross-sectional view of the covered stent of FIG. 8 in the radially expanded condition.

FIG. 11 is a graft illustrating the properties of the material forming the cover of the device of the present invention.

# DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

5 The present invention provides a composite covered stent which may be implanted intraluminally within a body vessel and disposed adjacent an occluded, weakened or otherwise damaged portion of the vessel so as to hold the vessel open. The covered stent is typically delivered intraluminally via a balloon catheter. The device is delivered in a compressed condition and once properly positioned may be deployed by radial expansion. The most common form of deploying the intraluminal device is by balloon expansion, however, the present invention may also be deployed by use of a self-expanding stent.

10 The composite intraluminal device 1 of the present invention takes the form of a stent 10 which may be of the type shown in FIG. 1 and a liner or cover 12 which may be of the type shown in FIG. 3. In use in a preferred arrangement the cover 12 is disposed over stent 10.

15 Referring specifically to FIG. 2, stent 10 is generally an elongate tube having a longitudinal stent axis 1. Stent 10 has opposed open ends 10a and 10b and a central lumen 10c therebetween. The body of stent 10 defines an opposed interior surface 11 and exterior surface 13 and is formed of a generally open configuration having a plurality of openings or passages through the body. These openings or passages provide for longitudinal flexibility of the stent as well as permitting the stent to be radially expanded once deployed in the body lumen.

20 The stent of the present invention is of the type more fully shown and described in International Patent Application No. WO 96/03092A1 published on Feb. 8, 1996, which along with its priority U.S. patent applications Ser. No. 282,181 filed Jul. 28, 1994 and Ser. No. 457,354 filed May 31, 1995, are incorporated by reference herein. The stent shown therein has a patterned shape having first and second meandering patterns extending orthogonally to each other. The particular meandering pattern and the opening or spaces therebetween allows the stent to be easily deployed through curved blood vessels as it renders the stent longitudinally flexible. Furthermore, the particular configuration of the stent 10 disclosed herein allows the stent to be radially expanded without significant reduction in longitudinal expanse.

25 While the present invention discloses a particular construction of stent 10, any open stent configuration well known in the prior art may be employed. For example, wire stents having bodies formed of helically coiled wire with spaces defined between the helixes may be employed in combination with the present invention. Furthermore, stents formed of tubes having etched or patterned slots therethrough may also be employed. Such stents are well known in the art and are described in the above-incorporated U.S. patents.

30 Stent 10 may be employed in combination with liner or cover 12 shown in FIG. 3. Cover 12 may be applied, in a preferred embodiment, over tubular stent 10 so as to fully circumferentially surround stent 10. While the preferred embodiment contemplates employing cover 12 about the exterior surface 13 of stent 10 as shown in FIG. 1, it is also contemplated that cover 12 in the form of a liner may be placed about the interior surface 11 of stent 10. The cover 12 thereby forms an effective barrier about stent 10 preventing excessive cell or tissue ingrowth or thrombus formation through the expanded wall of tubular stent 10. However, in order for cover 12 to function effectively in combination with stent 10, cover 12 must exhibit sufficient expansion

capabilities so as to enable the cover 12 to expand along with the radial expansion of stent 10.

The present invention contemplates use of a polymer material for cover 12 which exhibits sufficient expansion capabilities once positioned about stent 10. Such materials include extrudable, biocompatible polymers which exhibit or can be formed with a high degree of molecular orientation in one direction, i.e. material which is highly uniaxially oriented. These polymers exhibit the ability to expand in a direction substantially transverse to the direction of the uniaxial orientation. In the manufacture of polymer sheets, films and the like, typically the direction of orientation is the direction in which the material is formed. This is referred to as the machine direction (arrows M, FIG. 3). As the formation of the cover is typically accomplished by an extrusion process, the material is extruded along a longitudinal axis defining the machine direction. Material having uniaxial orientation in the machine direction would exhibit expansion in a direction substantially perpendicular thereto.

In a preferred embodiment of the present invention, cover 12 may be formed from uniaxially oriented expanded polytetrafluoroethylene (ePTFE). As is well known in the art ePTFE films or sheets may be formed in a paste extrusion process. Paste extrusion yields a PTFE product in a "green" state. Once the lubricant is removed, such a material is highly friable, that is, the material is subjected to crumbling if handled and would not be useful in certain applications requiring structural strength. However, the green material being highly uniaxially oriented (along the machine direction), may be expanded or stretched in a direction transverse to the machine direction. Normally to expand PTFE, the material is heated and expanded longitudinally to yield ePTFE. The resulting material is more stable and less friable and may be more easily handled. This is due to the node and fibril structure resulting from longitudinal expansion. This structure is shown in FIG. 3A. However, once sintered, such ePTFE material does not exhibit the ability to be further expanded or stretched. The present invention employs unsintered ePTFE, which has been processed by heating, only to the extent necessary to yield a stable non-friable material. PTFE generally requires sintering at its melting point, i.e. about 327° C. to attain structural properties. The present covers are heated to a temperature insufficient to sinter the product, i.e. generally below about 327° C. If temperatures are used at or beyond the normal sintering range, it must be for a time insufficient to effectuate sintering. Once heat conditioned in this manner, this material still exhibits the ability to be stretched or expanded in a transverse direction and exhibits sufficient radial strength for purposes of the present invention.

Thus, as shown in FIG. 3, ePTFE cover 12 having been extruded in its longitudinal direction along longitudinal expanse  $l_1$  would exhibit enhanced expansion capabilities along its transverse expanse  $t_1$ .

It has been found that certain commercially available PTFE materials exhibiting such properties may be employed in combination with the present invention. For instance, polytetrafluoroethylene tape may be used in combination with the present invention. The manufacture of such a tape is shown and described in U.S. Pat. No. 5,474,727 to Perez and U.S. Pat. No. 5,175,052 to Tokuda, each of which is incorporated by reference herein. The tape manufactured by the process described in the above-incorporated patents results in porous tape having little or no expansion capabilities in the longitudinal direction but exhibiting superior expansion capabilities in a direction substantially transverse thereto.

In order to employ such ePTFE tape as a cover for a stent 10, a segment thereof forming cover 12 is provided. Referring to FIGS. 3-5, cover 12 is positioned so that its longitudinal expanse  $l_1$  aligns with the longitudinal stent axis  $l_s$  of stent 10. In preferred form, the cover 12 is wrapped around the exterior surface of stent 10 so that opposed longitudinal edges 12a and 12b overlies each other forming a seam 14. Edges 12a and 12b may be adhered to one another so as to provide a closed seam. Adhering techniques such as a compression or adhesive bonding or anchoring may be employed to form closed seam 14. It is contemplated that weak electrostatic forces may be employed to bond together longitudinal edges 12a and 12b. No chemical bonding is necessary to form closed seam 14. Furthermore, an adhesive which will wet the material may also be applied so as to form an adhesive bond between the overlapped edges 12a and 12b. While cover 12 is shown attached to stent 10 by bonding overlapped edges 12a, 12b to form seam 14, it is further contemplated that cover 12 may be adhered to stent 10 at one or more locations therealong. Such securement is shown and described in commonly assigned U.S. patent application Ser. No. 08/721,834 filed at an even date herewith (as attorney docket no. 760-2) and entitled "Stent/Membrane Composite Device" which is incorporated by reference herein.

Once positioned about compressed stent 10, the ability of the material forming cover 12 to expand in a transverse direction allows the cover to be radially expanded upon the radial expansion of stent 10. Upon such radial stent expansion, either by balloon inflation or by self-expanding capabilities, cover 12 will expand transversely from a transverse dimension  $t_1$  to a transverse dimension  $t_2$  which is greater than  $t_1$ . As particularly shown in FIGS. 4 and 5, the transverse expanse  $t_1$  of cover 12 forms the circumferential component of the cover 12 about the compressed stent 10. Upon the radial expansion of stent 10, the ability for the transverse component of cover 12 to expand from a dimension  $t_1$  to a dimension  $t_2$  allows this cover to expand radially with the expansion of stent 10. Thus, as shown in FIG. 5, cover 12 expands to a circumferential dimension of  $t_2$  about expanded stent 10.

The ability of highly uniaxially oriented materials such as ePTFE to expand only in the direction transverse to the direction of extrusion (machine direction) allows the material to be used as a cover in a second embodiment of the present invention.

Referring now to FIG. 6, a further cover 12' which is similar to cover 12 shown in FIG. 3, includes a longitudinal expanse  $l_1'$  and a transverse expanse  $t_1'$ . As mentioned above, given the highly uniaxially oriented nature of the material, cover 12' may be expanded in a transverse direction. In this embodiment of the present invention, cover 12' is transversely expanded prior to placement about stent 10. As shown in FIG. 7, cover 12' is expanded transversely to a transverse dimension of  $t_2'$ . FIG. 6A shows the structure of the material so expanded where the machine direction is denoted by arrow M and the transverse stretched direction is denoted by arrow T. Such transverse expansion causes a corresponding reduction in the longitudinal expanse of cover 12' to a dimension of  $l_2'$  which is less than  $l_1'$ . Stent 10 is then aligned with cover 12 so that its longitudinal stent axis  $l_s$  extends along the transverse dimension  $t_2'$  of cover 12 as shown in FIG. 8. Cover 12' is then wrapped about stent 10 so that the transverse edges 12c' and 12d' overlap forming a closed seam 14. The overlapped transverse edges 12c' and 12d' may be secured in a manner similar to that described above with respect to the previous embodiment of the present invention.

While the highly uniaxially oriented material forming cover 12 exhibits little or no expansion capabilities along the longitudinal axis (machine direction, arrows M, FIGS. 6 and 7), if such material has been previously expanded transversely as described herein, the expanded material will, upon longitudinal stretching, stretch back to its original length. By employing the material as so described, the radial expansion of stent 10 can be controlled.

As shown in FIG. 9, with the stent 10 positioned with respect to cover 12' as described with respect to FIG. 8, radial expansion of stent 10 from the compressed condition shown in FIG. 9 to the expanded condition shown in FIG. 10 results in a corresponding expansion of the expanded cover 12'. Such expansion occurs along the longitudinal expanse of cover 12'. Since transversely expanded cover 12' is expandable along its longitudinal expanse only to its original length  $l_1'$ , the radial expansion of stent 12 supported thereunder will therefore be limited. Upon radial expansion of stent 12, the stent will only be expanded to an extent where cover 12' expands to a longitudinal dimension of  $l_1'$ . Further expansion of stent 10 is limited as cover 12 has reached its maximum expansion capability. By controlling the expansion properties of cover 12 control of the expansion of stent 10 may be achieved.

As cover 12' returns to its original length  $l_1'$  upon expansion of stent 10, shortening of its transverse expanse  $t_2'$  back to transverse expanse  $t_1'$  will occur. This will result in shortening of the cover about the stent 10. Such effects of shortening can be reduced by placing stent 10 with the stent axis  $l_1'$  slightly orthogonal with respect to transverse extent  $t_2'$ . While still providing a limit to the expansion of stent 10, the adverse effects of shortening will be thereby reduced.

The present invention is described in its preferred embodiment employing ePTFE as the material forming covers 12 and 12'. As ePTFE is highly uniaxially oriented along its machine direction, it exhibits the desirable expansion properties described herein. However, the present invention is not limited to solely ePTFE. Other expandable biocompatible polymer materials, such as polyurethane, which exhibit a high degree of uniaxial orientation in the direction of extrusion of the material may also be employed in combination with the present invention. Such materials are useful in the present invention in that the materials exhibit different stress properties in a direction along the longitudinal axis and in a direction transverse thereto. The characteristics of materials useful in the present invention are shown in the graph of FIG. 11 which is a relative schematic representation, where stress of the material is plotted along the y axis while strain is plotted along the x axis. Curve 20 shows the stress/strain relationship of the material along the machine direction while curve 30 shows the stress/strain characteristics of the material in a direction 90° with respect thereto. Materials exhibiting such properties will be useful in the composite device of the present invention. For example, such other materials may include polyesters such as polyethylene terephthalate (PET), polypropylenes, polyamides, nylons, and copolymers and mixtures thereof, among others.

The present invention farther contemplates incorporating various biological agents in the cover. Agents such as collagen and/or heparin or other drugs or agents may be incorporated into cover 12 for various known therapeutic purposes. Such combinations are shown and described in commonly assigned International Patent Application No. WO 95/29647, published on Nov. 9, 1995 and its priority U.S. applications Ser. No. 235,300 filed Apr. 29, 1994 and Ser. No. 350,233 filed Dec. 6, 1994 which are incorporated by reference herein.

Various changes and modifications can be made to the invention, and it is intended to include all such changes and modifications as come within the scope of the invention as is set forth in the following claims.

5 What is claimed is:

1. A composite intraluminal device comprising:
  - an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis; and
  - 10 a stent cover positioned about the stent and which is formed of unsintered ePTFE which is expandable upon said radial expansion of said stent,
 wherein said stent covering includes an elongate segment of said unsintered ePTFE having an original longitudinal expanse, said segment being expanded in a
  - 15 transverse direction so as to reduce said original longitudinal expanse, said segment being positioned generally transverse to said longitudinal stent axis, and being expandable longitudinally upon said radial expansion of said stent to return said expanded segment to said original longitudinal expanse to thereby control said radial expansion of said stent.
2. A composite intraluminal device of claim 1 wherein said stent is radially expandable from a first compressed state permitting intraluminal delivery to a second expanded
  - 25 state permitting intraluminal deployment.
3. A composite intraluminal device of claim 1 wherein said elongate segment is generally uniaxially oriented along said original longitudinal expanse.
4. A composite intraluminal device of claim 1 wherein
  - 30 said segment is joined about said stent along a seam formed by opposed overlapped transverse ends of said segment.
5. A method of forming an intraluminal device comprising the steps of:
  - providing an elongate radially expandable tubular stent;
  - 35 forming a stent cover from a longitudinal segment of unsintered ePTFE having a first longitudinal expanse and a transverse expanse,
  - expanding said segment along said transverse expanse to provide a second transverse expanse greater than said
  - 40 first transverse expanse and a second longitudinal expanse less than said first longitudinal expanse; and
  - applying said expanded segment about said stent, with said second transverse expanse extending longitudinally along said elongate stent.
6. A method in accordance with claim 5 wherein said
  - 45 applying step includes wrapping said cover exteriorly about said stent.
7. A method in accordance with claim 6 wherein said wrapping step further includes:
  - 50 overlapping opposed longitudinal of said stent cover.
8. A method in accordance with claim 7 further including the step of:
  - securing said overlapped longitudinal ends of said stent cover together.
9. A method of claim 8 wherein said securing step
  - 55 includes: adhesively securing said overlapped longitudinal ends.
10. A method in accordance with claim 8 wherein said
  - 60 securing step includes: compressively securing said overlapped longitudinal ends.
11. A method in accordance with claim 6 wherein said wrapping step includes:
  - 65 wrapping said expanded segment about said stent with said second longitudinal expanse extending generally transverse to said elongate stent.



12. An intraluminal stent assembly comprising:

a radially expandable stent having a longitudinal stent axis;

a stent cover positioned about said stent and being formed of a generally uniaxially oriented polymer, said stent cover being oriented in a first direction and expanded in a second direction transverse to said first so as to decrease the length of said stent cover from its original length, said longitudinal axis of said stent being aligned with said second direction, so that said stent cover is

10

expandable in said first direction to its original length  
upon said radial expansion of said stent to control said  
radial expanse of said stent.

13. A stent assembly of claim 12 wherein said expanded  
5 stent cover is expandable in its first direction up to its  
original length.

14. A stent assembly of claim 13 wherein said uniaxially  
oriented polymer includes unsintered ePTFE.

\* \* \* \* \*

15. A composite intraluminal device comprising:  
an elongate radially expandable tubular stent having an interior luminal surface and an  
opposed exterior surface extending along a longitudinal stent axis; and  
an elongate stent cover applied longitudinally about the stent and which is formed of  
unsintered ePTFE having a longitudinal expanse and a transverse expanse as applied to said stent  
and which is expandable along said transverse expanse from said applied transverse expanse  
upon radial expansion of said stent.
16. A composite intraluminal device of claim 15 wherein said stent is radially expandable  
from a first state permitting intraluminal delivery to a second expanded state defining  
intraluminal deployment.
17. A composite intraluminal device of claim 16 wherein said stent cover is applied about  
said stent in said first state and is expandable along said transverse expanse upon expansion of  
said stent to said second state.
18. A composite intraluminal device of claim 17 wherein said stent cover is joined about said  
stent along a seam formed by opposed overlapped longitudinal edges thereof.
19. A composite intraluminal device of claim 18 wherein said seam is formed by  
compression of said overlapped edges.
20. A composite intraluminal device of claim 18 wherein said seam is formed by adhesively  
joining said overlapped edged.
21. A composite intraluminal device of claim 17 wherein said stent cover is generally  
uniaxially oriented along the longitudinal direction.

A composite intraluminal device is deployable within a body vessel. The composite device includes an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis. A stent cover is formed of unsintered ePTFE which is expandable. The stent cover is positioned about the stent so as to permit expansion of the cover upon the radial expansion of the stent.

1. A composite intraluminal device, comprising:  
a. an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis;  
b. a stent cover formed of unsintered ePTFE which is expandable;  
c. the stent cover positioned about the stent so as to permit expansion of the cover upon the radial expansion of the stent.

FIG. 1

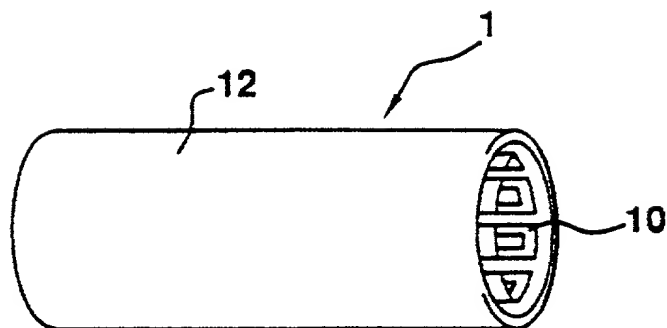


FIG. 2

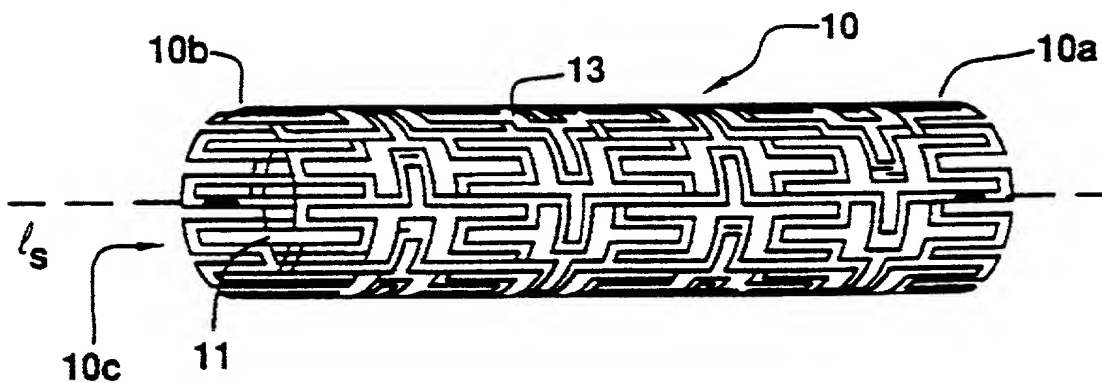


FIG.3

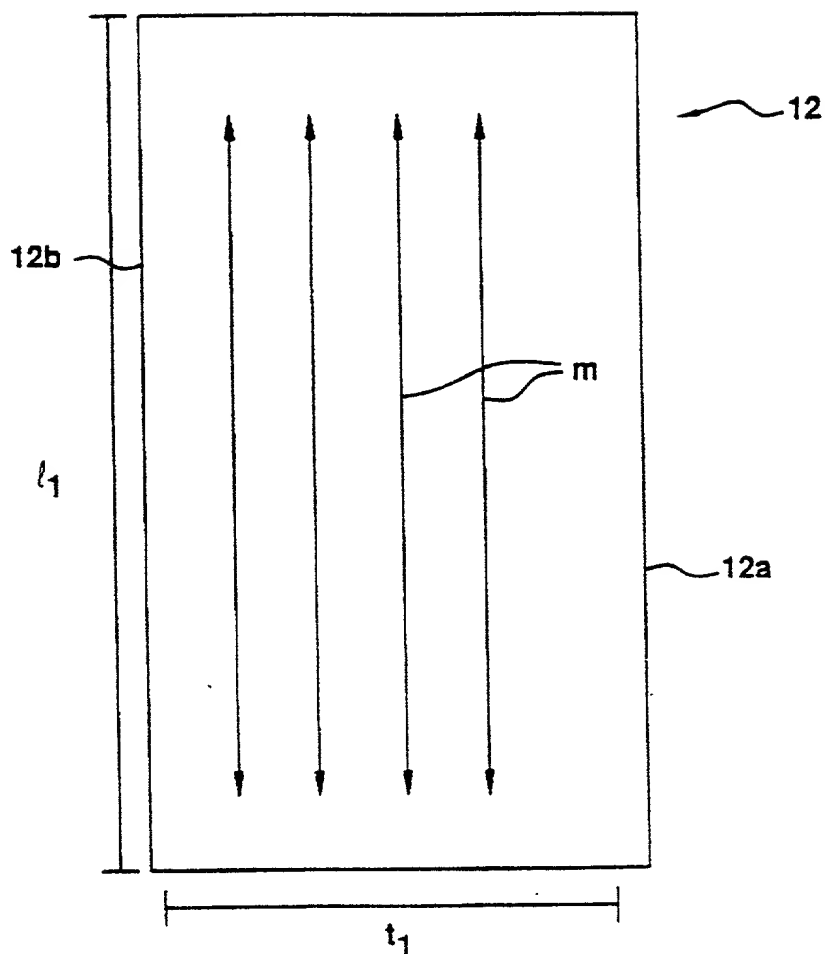


FIG.4

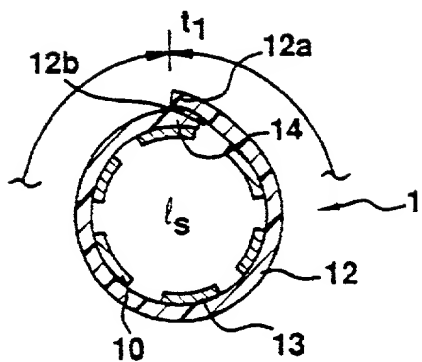
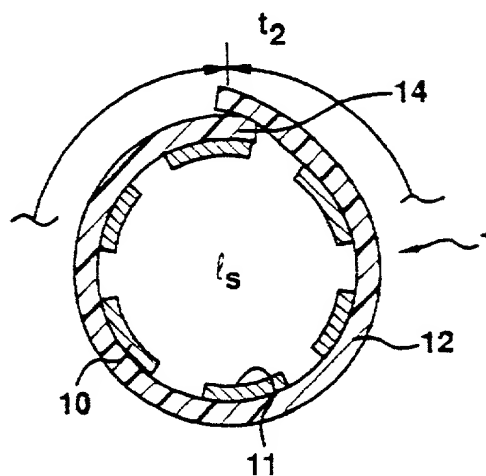


FIG.5



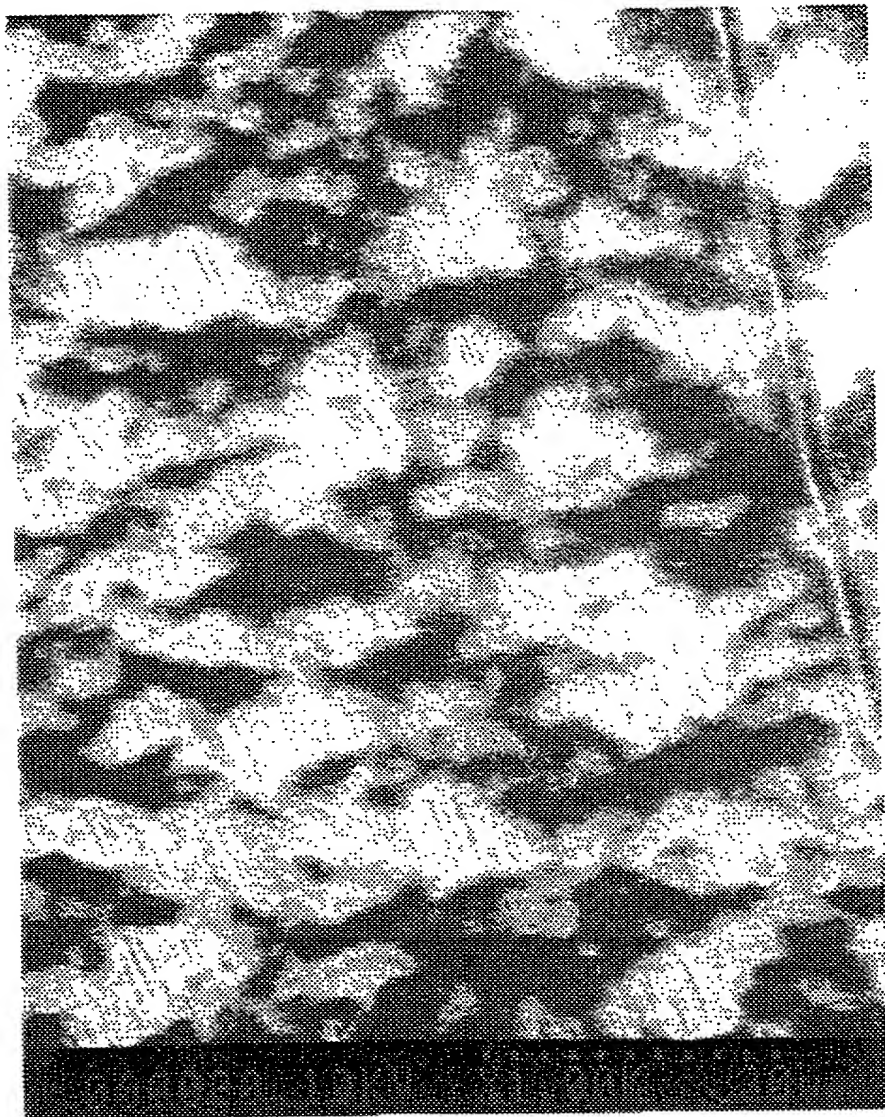


FIG.3A

FIG. 6

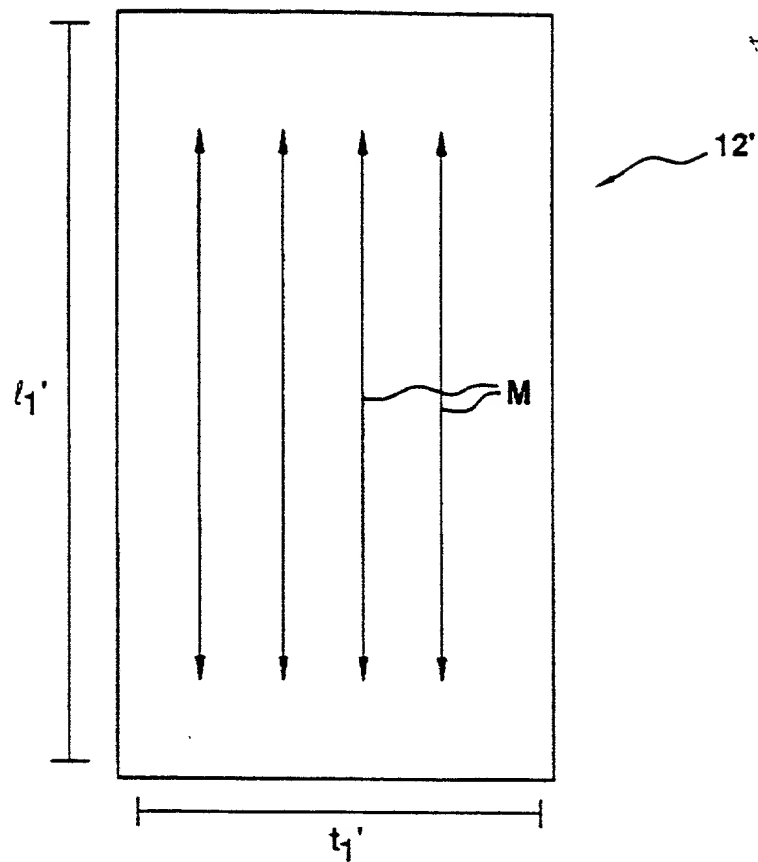
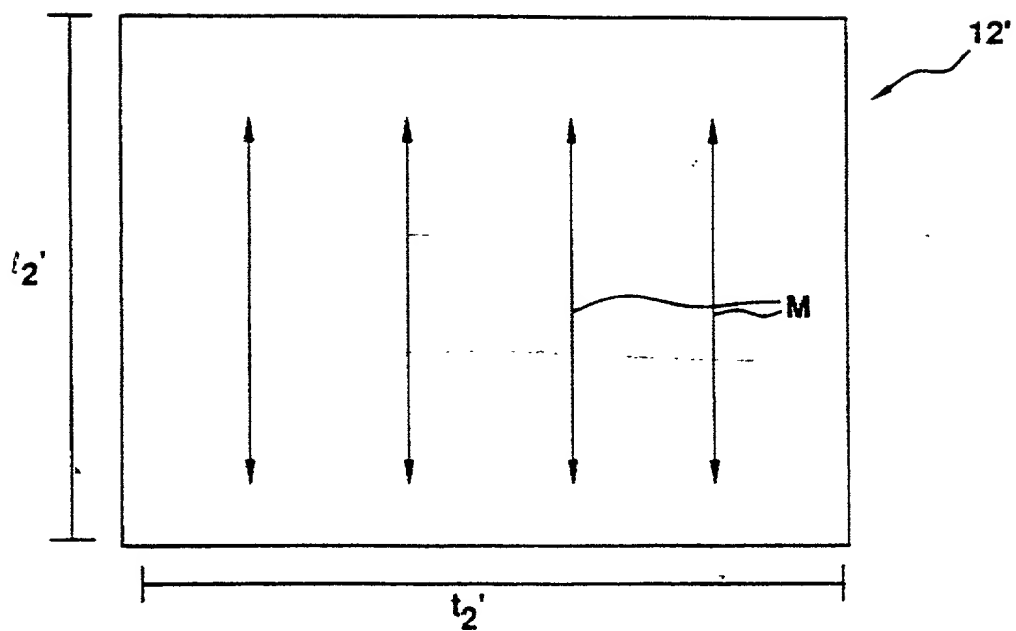


FIG. 7





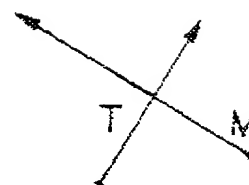
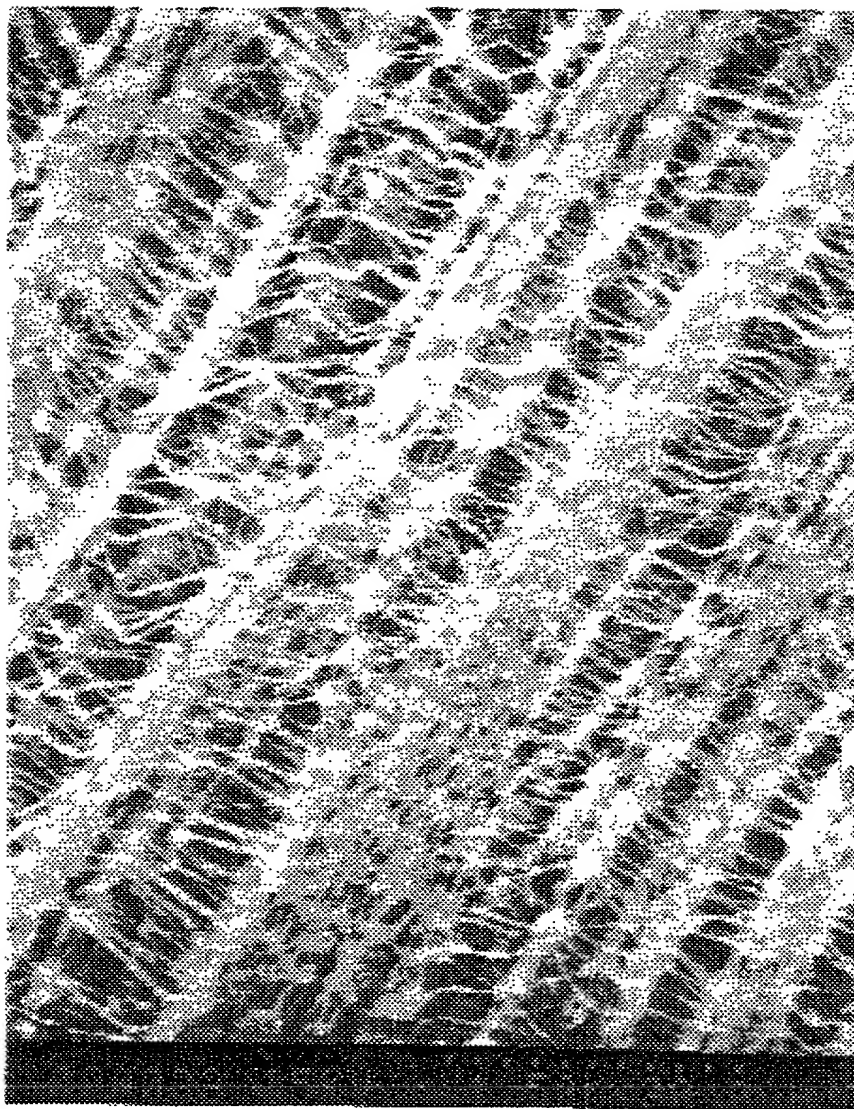


FIG.6A

FIG.8

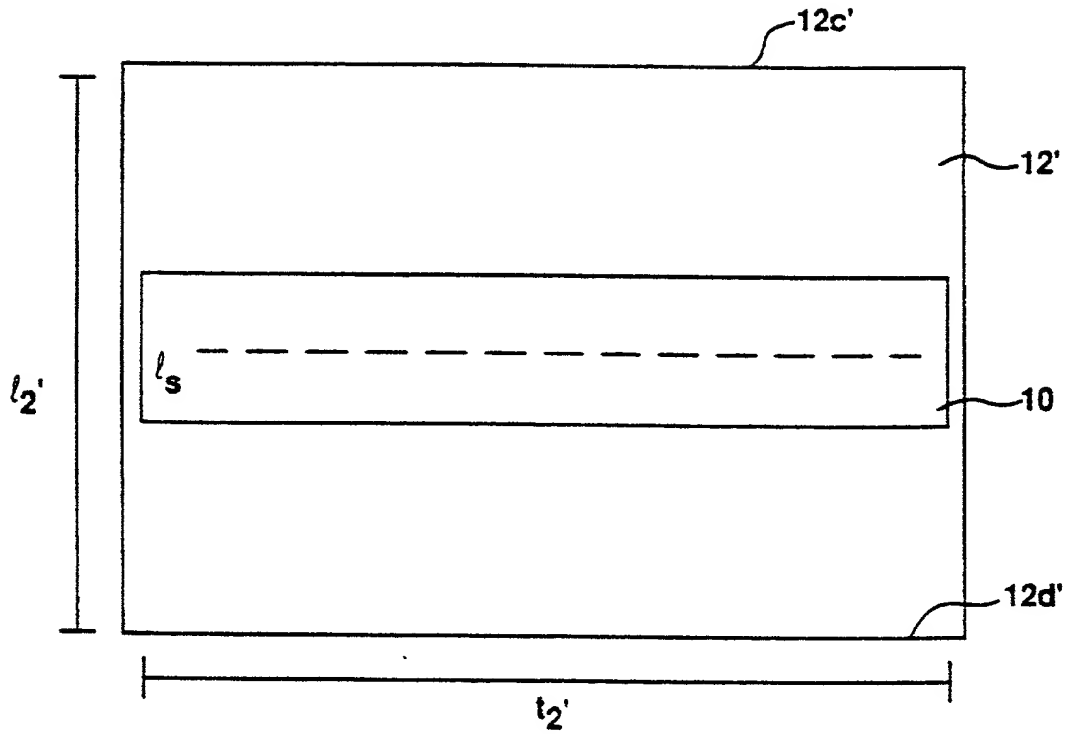


FIG.9

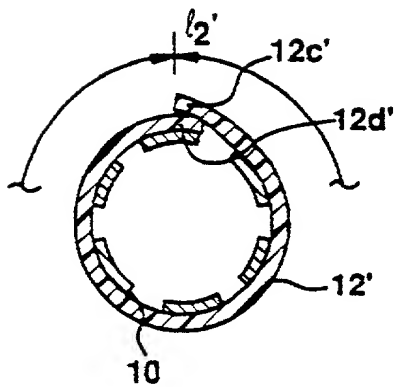


FIG.10

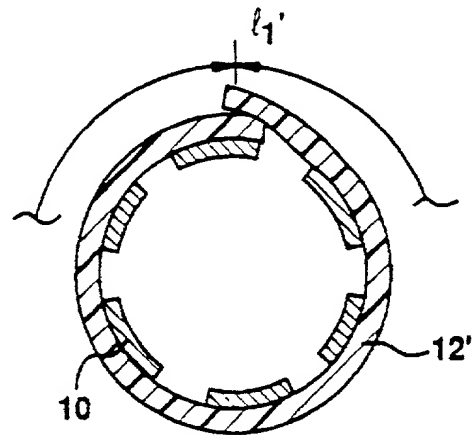
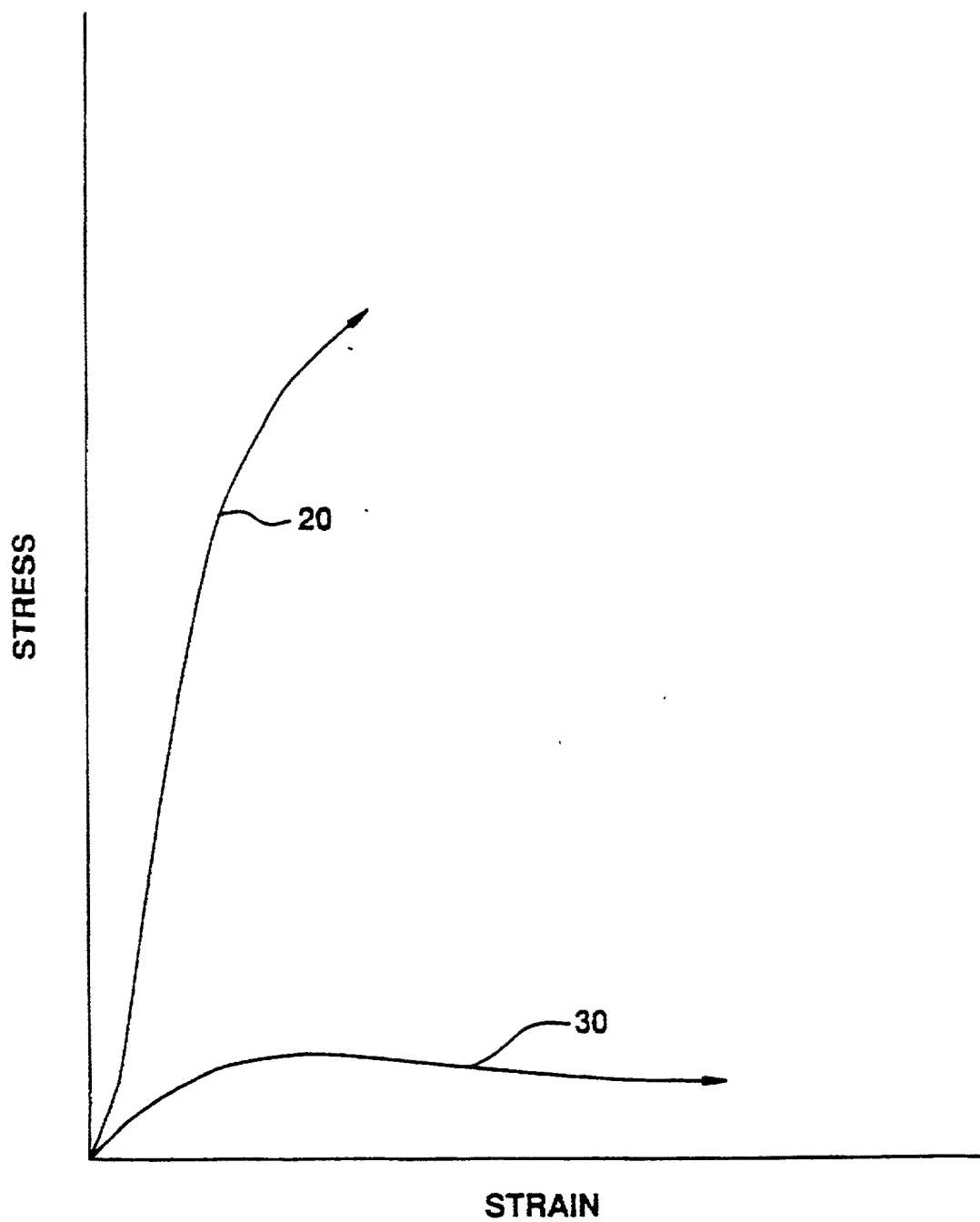
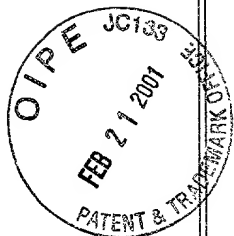


FIG. 11





**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application for Reissue of U S. Patent  
No. 5,824,046

Applicant(s): Smith, et al.

Serial No: 09/691,782

Filing Date: October 19, 2000

Docket: 760-3

Issued: October 20, 1998

For: IMPROVED COVERED STENT

Dated: February 16, 2001

I hereby certify this correspondence is being deposited with  
the United States Postal Service as first class mail, postpaid in  
an envelope, addressed to Assistant Commissioner of Patents,  
Washington, D C 20231

Dated February 16, 2001

Signature B. Kemmlein

Assistant Commissioner for Patents  
Washington, DC 20231

**REISSUE DECLARATION**

Sir:

We, Scott R. Smith, David Sogard, and Susan Shoemaker, residents of Chaska, MN, Edina, MN and Elk River, MN respectively, declare we are citizens of the United States, and:  
that we believe we are the original and first inventors of the subject matter claimed in U.S. Patent No. 5,824,046 (hereinafter the '046 patent) entitled "Covered Stent";  
that we have reviewed and understand the specification of the accompanying reissue application, including the claims;  
that we believe that we are the original and first inventors of the subject matter which is claimed and for which the reissue patent is sought; and  
that we acknowledge our duty to disclose to the U.S. Patent and Trademark Office all information known to us to be material to patentability as defined in 37 C.F.R. §1.56.

We further declare that we believe the above identified original patent to be partly inoperative or invalid by reason of our claiming less than we had a right to claim in the original patent. Specifically, we believe that the original patent is partly inoperative or invalid for including limitations in the claims that were not required by the prior art.

After reviewing the specification and issued claims of the '046 patent and consulting with the patent attorneys of SCIMED Life Systems, Inc. and of Hoffmann & Baron, LLP, who are outside counsel for SCIMED Life Systems, Inc., the assignee of the '046 patent, we came to the realization that we had inadvertently failed to claim certain broad aspects of our invention.

We believe that the error constituted inadvertent failure to appreciate the full scope of the claims which were available in view of the prior art, and that the error arose without any deceptive intent on our part.

Claim 15 of the re-issue application corresponds generally with claim 1 of the '046 patent. Claim 15, however differs from claim 1 in at least one respect, including, for example: Claim 1 describes an elongate segment; said segment being expanded in a transverse direction so as to reduce the original longitudinal expanse of the ePTFE cover. More specifically, claim 1 stated that the elongate segment was, "expandable longitudinally upon said radial expansion of said stent to return said expanded segment to said original longitudinal expanse to thereby control said radial expansion of said stent". This language of claim 1 has not been included in claim 15, and has been replaced by more functional language regarding the expansive characteristics of the PTFE cover of the stent.

We believe that this limiting language regarding the elongate segment was not necessary to be included in claim 1 with regard to its patentability over the prior art. More specifically, it is clear that there is nothing in the prior art which discloses, teaches, or suggests covering a stent at a first diameter with a transversely-expanded and transversely-aligned sheet of unsintered ePTFE so that the sheet can itself expand with a radial expansion of the stent to a second larger diameter. These limitations are included in reissue claim 15.

These and other limitations in the issued claims resulted from our apparent failure and the failure of patent counsel to fully appreciate the limiting nature of the claim limitations, as well as failure to fully appreciate the full scope of the invention as taught by the specification.

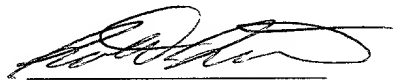
Furthermore, all errors being corrected in the present reissue application arose without any deceptive attempt on our part.

We declare that all statements made herein, of our own knowledge, are true, and that all statements made upon information and beliefs are believed to be true, and further that these statements were made after being warned that willful false statement and the like are punishable by fine or imprisonment, or both under 18 U.S.C. 1001, and that such false statements may jeopardize the validity of this application or any patent issuing thereon.

Respectfully submitted,

Name: Scott R. Smith

Signature:

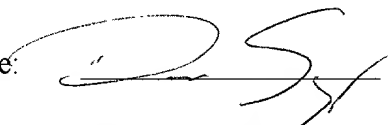


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16-Jun-2001

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Signature: 

Date: 2/1/01

Residence: 5809 Concord  
Edina, MN 55424

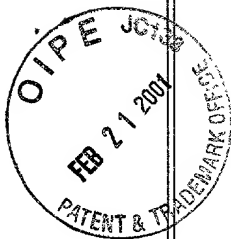
Name: Susan Shoemaker

Signature:   
190th SMS

Date: 1/16/01

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Elk River, MN 55330

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Smith et al.

Examiner: Unassigned

Serial No.: 09/691,782

Group Art Unit: 3738

Filed: October 19, 2000

Docket: 760-3 RES

For: COVERED STENT

Dated: February 16, 2001

I hereby certify that this correspondence is being deposited with United States Postal Service as first class mail, postpaid in an envelope, addressed to Commissioner For Patents, Washington, D C 20231

Dated February 16, 2001

Signed Barbara Kemmlein/

Commissioner For Patents  
Washington, D.C. 20231

**STATEMENT UNDER 37 C.F.R. § 3.73(b)**  
**ESTABLISHING RIGHT OF ASSIGNEE TO TAKE ACTION**

Sir:

SCIMED Life Systems, Inc., states that it is the assignee of the entire right, title and interest in the above-identified patent application, by virtue of the Assignment from the inventors of the application identified above. The Assignment was recorded in the U.S. Patent and Trademark Office on December 18, 1996 in Reel 8327, Frame 0114.

The undersigned is empowered to sign this statement on behalf of the assignee as evidenced by the attached authorization form.

Respectfully submitted,

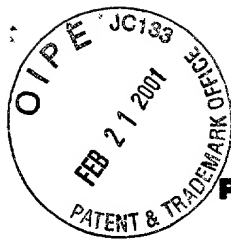
Luke R. Dohmen

Registration No. 36,783

Senior Patent Counsel

HOFFMANN & BARON, LLP  
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(973) 331-1700





Practitioner's Docket No. 760-3 RES

**PATENT**

### ASSENT BY ASSIGNEE FOR FILING OF REISSUE APPLICATION

NOTE: The written assent of all assignees, if any, owning an undivided interest in the original patent must be included in the application for reissue. 37 C.F.R. 1.172(a).

This is part of the application for a reissue patent filed herewith based on the original patent identified as follows:

Smith et al.  
Name of Patentee

5,824,046  
Patent Number

October 20, 1998  
Date Patent Issued

COVERED STENT  
Title of Invention

I am an assignee owning

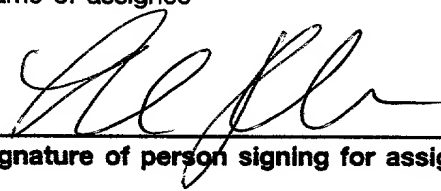
☒ an undivided interest to the above original patent.

☐ a \_\_\_\_\_% (per cent) interest in the above original patent.

I assent to the accompanying application for reissue.

Attached is a "Statement under 37 C.F.R. § 3.73(b) — Establishing Right of Assignee to Take Action."

SCIMED Life Systems, Inc.  
Name of assignee

  
Signature of person signing for assignee

Date: Feb 13, 01

Luke Dohmen, Senior Patent Counsel  
(type or print name and title of person signing for assignee)